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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,007	03/29/2001	Chunhua Yan	CL001205	4060

7590 06/18/2003

CELERA GENOMICS CORPORATION
45 West Gude Dr. C2-4#20
Rockville, MD 20850

EXAMINER	
PAK, MICHAEL D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/820,007	Applicant(s)	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 20 and 21, drawn to peptides, classified in class 530, subclass 350.

II. Claim 3, drawn to antibody, classified in class 530, subclass 387.1.

III. Claims 4, 5, 8-11, 22 and 23, drawn to nucleic acids, vectors, host cells, and methods of producing protein recombinantly, classified in class 435, subclass 69.1, for example.

IV. Claim 6, drawn to a gene chip, classified in class 536, subclass 24.1, for example.

V. Claim 7, drawn to transgenic animal, classified in class 800, subclass 8.

VI. Claim 12, drawn to method for detecting peptide, classified in class 435, subclass 7.1.

VII. Claim 13, drawn to method for detecting nucleic acid, classified in class 435, subclass 6.

VIII. Claims 14 and 15, drawn to method for identifying a peptide modulator with polypeptide, classified in class 436, subclass 501.

IX. Claim 16, drawn to method for identifying a binding agent, classified in class 435, subclass 7.2.

X. Claim 17, drawn to pharmaceutical composition comprising a binding agent, classification dependent upon structure of recited agent.

XI. Claim 18, drawn to method for treating disease comprising administering an agent, classification dependent upon structure of agent.

XII. Claims 19, drawn to method for identifying a peptide modulator with cell, classified in class 435, subclass 375.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-V and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the protein of Group I can be prepared by processes which are materially different from recombinant DNA expression of Group III, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group III can be used other than to make the protein of Group I, such in gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group I can be used in materially different methods other than to make the antibody of Group II, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group II can be used to obtain the DNA of Group III, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The gene chip of Invention IV is independent and distinct from the peptides of Invention I, the antibody of invention II, the transgenic animal of Invention V and the pharmaceutical composition

of Invention X, because the gene chip is not required for the manufacture of any of these other products. The gene chip is related to the nucleic acids of Invention III because the chip comprises the nucleic acids. However, the chip requires search and consideration of solid supports, which is not required for the search of the nucleic acids. Also, the gene chip and the nucleic acids are used in materially different methods. The transgenic animal of Invention V is independent and distinct from the peptides of Invention I, the antibody of invention II, the gene chip of Invention IV and the pharmaceutical composition of Invention X, because the transgenic animal is not required for the manufacture of any of these other products. The transgenic animal is related to the nucleic acids of Invention III because the animal comprises the nucleic acids. However, the animal requires search and consideration of transformation methods, which is not required for the search of the nucleic acids. Also, the animal and the nucleic acids are sued in materially different methods. The pharmaceutical composition of Invention X is independent and distinct from the other products, because it can be made without use of the other products. Also, it has a structure and activity that is different from those of the other products, and would require further search and consideration.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups VI-IX and XI – XII are directed to methods that are distinct both physically and functionally, and are not

required one for the other. Invention VI requires methods of detecting peptides, which is not required by any of the other groups. Invention VII requires measurement of nucleic acid expression, which is not required by any of the other groups. Invention VIII requires evaluation of peptide activity with the transporter, which is not required by any of the other groups. Invention IX requires evaluation of peptide binding, which is not required by any of the other groups. Invention XI requires search of patient populations suffering from a disease, which is not required by any of the other groups. Invention XII requires the peptide activity with the cell which is not required by any of the other groups. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I and each of VI, VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptides of Group I can be used to raise antibodies.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the agents of Group X can be used to label proteins *in situ*.

Inventions IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agents can be made synthetically.

The remaining pairs of Inventions are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of each Invention pair is not required by the method of each Invention pair.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney Justin Karjala on 14 June 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
14 June 2003